IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

ABBVIE INC.; ALLERGAN, INC.; DURATA THERAPEUTICS, INC.; ABBVIE PRODUCTS LLC; PHARMACYCLICS LLC; and ALLERGAN SALES, LLC,

Plaintiffs,

v.

GENTNER DRUMMOND, in his official capacity as Attorney General of the State of Oklahoma,

Defendant.

Case No. 5:25-cv-00726-PRW

Judge Patrick R. Wyrick

HEARING REQUESTED

PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION WITH BRIEF IN SUPPORT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Constitutional Provisions

Statutes

Regulations

PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION WITH BRIEF IN SUPPORT

Pursuant to Rule 65 of the Federal Rules of Civil Procedure, Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products LLC, Pharmacyclics LLC, and Allergan Sales, LLC (collectively "AbbVie"), hereby move for a preliminary injunction.

RELIEF SOUGHT AND GROUNDS FOR MOTION

AbbVie respectfully requests that the Court preliminarily enjoin the Oklahoma Attorney General from enforcing H.B. 2048 against AbbVie during the pendency of this litigation. The particular grounds for this relief—discussed in more detail below—are as follows: (1) AbbVie is likely to succeed on the merits of its claims that Oklahoma's H.B. 2048 is unconstitutional under the Supremacy Clause, Takings Clause, and Fourteenth Amendment Due Process Clause of the U.S. Constitution; (2) AbbVie will be irreparably harmed by H.B. 2048's enforcement because the challenged law deprives AbbVie of its constitutional rights and inflicts unrecoverable compliance costs; and (3) the balance of equities and public interest both weigh heavily in AbbVie's favor because Oklahoma has no interest in enforcing its invalid law.

INTRODUCTION

This case concerns Oklahoma's unconstitutional effort to change the terms of a federal program and compel unwilling drug manufacturers to transfer their products to private entities for private gain. Under the federal 340B drug-pricing program, participating manufacturers must merely "offer" their drugs at discounted prices to certain nonprofit healthcare entities. By doing so, manufacturers satisfy their 340B obligations.

Oklahoma's H.B. 2048, however, unilaterally moves Congress's goalposts. The state law strips drug manufacturers like AbbVie of their statutorily protected ability to impose reasonable conditions on their 340B offers. And it compels manufacturers to transfer their drug products at bargain-bin discounts to private entities—much to the benefit of opportunistic commercial pharmacies. That offends the Constitution in at least three different ways: It clashes with federal law, effects an improper taking, and imposes civil and criminal liability for violations of hopelessly vague provisions.

AbbVie now seeks preliminary injunctive relief. AbbVie has shown a strong likelihood of success on the merits of its constitutional challenges to H.B. 2048. And AbbVie will also suffer irreparable harm if Oklahoma's statute is enforced. For its part, Oklahoma would suffer no prejudice from an injunction of its unconstitutional law, and the public interest favors the preservation of constitutional rights and our federal structure. A preliminary injunction should issue.

STATEMENT OF FACTS

A. The 340B Program.

In 1992, Congress enacted Section 340B of the Public Health Service Act—known as the "340B Program"—to help a select group of nonprofit healthcare providers access prescription medications at steep discounts. *See* 42 U.S.C. § 256b. To compel drug manufacturers' participation, Congress made compliance with the 340B Program a mandatory prerequisite for participating in Medicaid and Medicare Part B—federal healthcare programs that account for an enormous chunk of the nation's drug market.

To enter the 340B Program, drug manufacturers sign a statutorily required, non-negotiable pricing "agreement" with the U.S. Department of Health and Human Services ("HHS"). *See Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011).[1] Those manufacturers must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). Only a narrow list of nonprofit healthcare providers qualify as "covered entities" eligible for those discounted prices. *Id.* § 256b(a)(4). For-profit entities—like commercial pharmacies—do not qualify. *See id.*

Congress imposed guardrails aimed at preventing covered entities from abusing the Program. The 340B statute bars covered entities from engaging in "diversion" by transferring discounted drugs to anyone other than an eligible patient. And it also prohibits covered entities from getting "duplicate discounts" by claiming both a 340B discount and a Medicaid rebate for the same drug. 42 U.S.C. § 256b(a)(5).

Congress vested exclusive 340B enforcement authority in HHS, which in turn delegated that authority to the Health Resources and Services Administration ("HRSA"). HRSA administers the Program through oversight, audits, and a formal dispute-resolution process. *Id.* § 256b(d). Violations by manufacturers may result in contract termination, Medicaid exclusion, or civil penalties. *Id.* §§ 256b(d)(1), (d)(3).

[1] Ex. 1 (Scheidler Decl.) at Ex. A (copy of pricing agreement).

B. The Rise of "Contract Pharmacies" and AbbVie's Response.

By its terms, the 340B Program applies specifically to covered entities operating only in-house pharmacies. But in 1996, HHS issued non-binding guidance purporting to allow covered entities without in-house pharmacies to contract with a *single* outside pharmacy to dispense 340B drugs, provided that the covered entity retains title to the drugs. 61 Fed. Reg. 43549, 43551–53 (Aug. 23, 1996). Things changed again when, in 2010, new HHS guidance purported to allow covered entities to contract with unlimited outside pharmacies—regardless of in-house capabilities, and often with pharmacies located hundreds of miles away. 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010).

Covered entities quickly exploited the 2010 policy shift—much to the benefit of commercial pharmacies. For-profit pharmacies like CVS and Walgreens began acquiring massive volumes of 340B drugs for pennies on the dollar, selling them at full price, and splitting profits with covered entities.[2] Between 2010 and 2024, covered entities' use of contract pharmacies ballooned by more than 12,000 percent.[3] And by 2023, 340B sales had reached an estimated $124 billion in gross profits.[4] Tellingly, when drug manufacturers revised their 340B policies to limit contract-pharmacy usage, CVS and Walgreens disclosed the change as a material risk to their business in their annual reports.[5]

---

2 Ex. 2 (2020 AIR Report) at 2–3, 4–9.

3 Ex. 3 (2025 BRG Report) at 2.

4 Ex. 4 (2024 IQVIA White Paper) at 2; *see also* Ex. 5 (2024 BRG Report) (tracking 340B Program's rapid recent growth compared to other federal programs).

5 *See* CVS Pharmacy 10-K (2022) at 22, https://tinyurl.com/mpwpre9x; Walgreens, Inc. 10-K (2022) at 28, https://tinyurl.com/mu6tfzcu.

Patients and the public do not benefit from this arbitrage scheme. Pharmacies generally charge patients or their insurers full price,[6] and insured patients actually pay *more* in out-of-pocket costs and premiums.[7] Meanwhile, HHS's Inspector General reported that contract-pharmacy arrangements greatly increase the risk of diversion because contract pharmacies cannot verify 340B eligibility in real time and dispense from their general inventory rather than from a segregated stock of 340B-priced drugs.[8]

AbbVie and other manufacturers responded to the explosion in contract-pharmacy abuse by adjusting their 340B policies. In 2023, AbbVie announced its 340B Program Integrity Initiative.[9] The policy (most recently updated in July 2025) allows hospital covered entities to direct transfer of AbbVie's 340B-priced drugs to their in-house pharmacies. If a covered entity lacks an in-house pharmacy, it may direct transfer to a single contract pharmacy of its choice within 40 miles, provided that it also supplies limited claims data. AbbVie is committed to ensuring each hospital covered entity has at least one pharmacy location to receive and dispense discounted drugs and, if necessary, will work with covered entities to identify alternatives to the 40-mile requirement. Plus, federal

---

6 Ex. 6 (2022 IQVIA White Paper) at 9 (reporting that patients receive discounts at contract pharmacies less than 1.4% of the time).

7 Ex. 7 (*Hearing on H.266 Before the H. Comm. on Health Care*, 2025-2026 Sess. (Vt. Feb. 26, 2025) (testimony of BlueCross BlueShield of Vermont)) at 9.

8 Ex. 8 (2014 HHS OIG Report) at 1; *see also* Ex. 9 (2011 GAO Report) at 28; Ex. 10 (2018 GAO Report) at 43–44 (flagging contract-pharmacy abuse and reporting that most diversion findings in HRSA audits involved contract pharmacies); Ex. 11 (Hr'g Tr., *AbbVie Inc. v. Murrill* (W.D. La.)) at 59:20–60:13 (counsel for covered entities acknowledging use of "replenishment model" in which pharmacies do not physically distinguish 340B and other drugs); Ex. 12 (Intervenor Defs.' MSJ Reply Br., *Murrill*) at 4–5 (same).

9 *See* Ex. 1 at Exs. B, E (AbbVie's letters to covered entities regarding new policy).

grantees may place orders for direct delivery to an unlimited number of contract pharmacies as long as the grantee submits claims data and registers with a provided free web-based platform. AbbVie continues to offer unlimited 340B-priced drugs to all covered entities, as the 340B statute requires. Accordingly, AbbVie's policy in no way affects patient access to 340B-discounted drugs.

C. Federal Courts Approve Contract-Pharmacy Limitations.

In December 2020, HHS issued an "Advisory Opinion" requiring manufacturers to transfer their products to an unlimited number of for-profit commercial pharmacies.[10] Litigation ensued, and manufacturers prevailed in two Courts of Appeals. *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023); *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024). The Third Circuit endorsed manufacturer policies that limit the indiscriminate transfer of discounted drugs to commercial pharmacies, emphasizing that Congress intentionally "chose not to" impose contract-pharmacy obligations on manufacturers. *Sanofi*, 58 F.4th at 703–07; *see id.* at 704 ("[Congress] had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies."). The D.C. Circuit agreed: The 340B Program "merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount." *Novartis*, 102 F.4th at 460. It does not "subject manufacturers to whatever delivery conditions any covered entity might find most convenient." *Id.* at 461.

[10] HHS Advisory Opinion No. 20-06 (Dec. 30, 2020), https://tinyurl.com/2ca6rmnm.

So long as a manufacturer's policy does not prevent a bona fide offer, it is lawful—even if it limits delivery to a single pharmacy. *Id.* at 463–64.

In the aftermath of those federal decisions, states started enacting their own 340B contract-pharmacy laws purporting to mandate what HHS could not. The Southern District of West Virginia preliminarily enjoined one such state contract-pharmacy law (a statute closely resembling Oklahoma's H.B. 2048) on preemption grounds. *PhRMA v. Morrisey*, 760 F. Supp. 3d 439, 452–60 (S.D. W. Va. 2024). *Morrisey* rebuffed the state's argument that its law was a mere "delivery" regulation consistent with 340B's requirements. *Id.* at 455–56. And it soundly rejected other courts' contrary decisions, criticizing their cursory analysis and failure to adhere to Supreme Court precedent. *Id.* at 458–59.

D. Oklahoma Attempts to Undo Federal Rulings.

In May 2025, Oklahoma enacted H.B. 2048—a law that, among other things, imposes new 340B contract-pharmacy obligations on manufacturers. It did so over the objections of its governor: Recognizing that the 340B Program "is in deep need of reform at the *federal* level," Governor Stitt vetoed the controversial bill and criticized the legislature for wrongly "insert[ing] itself" into a dispute where it did not belong.[11] Oklahoma's legislature ignored those concerns and overrode the veto. H.B. 2048 takes effect on November 1, 2025. AbbVie now challenges that law's constitutionality.

H.B. 2048 eliminates AbbVie's ability to place reasonable conditions on 340B offers and imposes the very obligations that *Sanofi* and *Novartis* rejected. Oklahoma's law

[11] H.B. 2048 Veto Message (May 17, 2025) (emphasis added), https://tinyurl.com/5fsuaeh4.

states that drug manufacturers cannot "deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to a 340B entity, unless such receipt is prohibited by [HHS]." H.B. 2048 § 4(A). H.B. 2048 goes on to define "340B entity" to include both covered entities *and* "any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B drug discount program." *Id.* § 2(2). It also defines "340B drug" as "a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to [the federal 340B statute]." *Id.* § 2(1). So H.B. 2048 forces manufacturers to allow commercial pharmacies to acquire drugs defined by their 340B discount prices—a radical departure from the 340B Program that Congress designed.

Oklahoma's law then goes even further. In a separate catch-all provision, H.B. 2048 baldly states that manufacturers "shall not interfere with a pharmacy contracted with a 340B entity." *Id.* § 4(B). Because "340B entity" already (by definition) includes contract pharmacies, this provision confusingly prohibits "interference" with even third-party pharmacies that do not dispense 340B drugs. *See id.* §§ 2(2), 4(B). Finally, Oklahoma requires all 340B entities to "contract with any willing pharmacy upon mutually agreeable terms within a fifteen-mile radius of the 340B entity's location." *Id.* § 4(C). That provision is novel: Nobody—not any of the other states with contract-pharmacy laws, not HHS or HRSA, and certainly not Congress—has ever suggested that contract-pharmacy arrangements are a mandatory part of the 340B Program. Oklahoma stands alone.

H.B. 2048 also creates its own enforcement regime. The Oklahoma Attorney General is authorized to "establish rules and regulations" interpreting H.B. 2048's

provisions about manufacturers. *Id.* § 5(B). And the Attorney General is further empowered to enforce the law against manufacturers and impose civil fines of up to $10,000 per violation. *Id.* Worse, Oklahoma law imposes *criminal* misdemeanor liability for violations of H.B. 2048. *See* Okla. Stat. tit. 36, § 117.

LEGAL STANDARD

The party seeking a preliminary injunction must establish "(1) a likelihood of success on the merits; (2) a likelihood that the movant will suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in the movant's favor; and (4) that the injunction is in the public interest." *RoDa Drilling Co. v. Siegal*, 552 F.3d 1203, 1208 (10th Cir. 2009) (citation omitted). The third and fourth factors merge where, like here, the government is the opposing party. *Does 1-11 v. Bd. of Regents of Univ. of Colo.*, 100 F.4th 1251, 1267 (10th Cir. 2024).

ARGUMENT

The Court should preliminarily enjoin Oklahoma's law. If allowed to take effect, H.B. 2048 will visit unconstitutional and irreparable harms upon AbbVie. Among other things, Oklahoma's law changes the terms of a purely federal Program and compels AbbVie to transfer its drugs to private entities for private gain. AbbVie will never get an opportunity to recover its losses after the fact—and the public will not see any benefit from those compelled transfers.

I. ABBVIE IS LIKELY TO SUCCEED ON THE MERITS.

AbbVie will likely succeed in its challenge to H.B. 2048 because Oklahoma's law is unconstitutional three times over: It is preempted by federal law, it effects an improper taking of private property, and it is impermissibly vague.

A. Oklahoma's Law Is Preempted.

Federal law preempts H.B. 2048. Under the Constitution's Supremacy Clause, federal law is "the supreme law of the Land." U.S. Const. art. VI, cl. 2. So "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992). H.B. 2048 is preempted because it intrudes on a federal field and conflicts with the text and purpose of the 340B statute.

Field Preemption. Congress occupies an entire regulatory field—and displaces any state laws in that field—when its framework is "so pervasive" that there is "no room for the States to supplement it," or where the federal interest is "so dominant" that state law is precluded. *Arizona v. United States*, 567 U.S. 387, 399 (2012). That describes the 340B Program. Congress created a single comprehensive federal scheme with a finite set of obligations, eligibility criteria, and enforcement mechanisms. And unlike Medicaid, Congress never invited States to participate in administering the 340B Program. Any state regulation that targets or alters the 340B Program in particular—such as by imposing new 340B-specific obligations—unlawfully encroaches upon that federally preempted 340B field.

Oklahoma does just that with H.B. 2048. Its law operates entirely within the federally occupied 340B field and exclusively regulates the very heart of that field: the terms of a 340B offer. Indeed, H.B. 2048 could not even exist as a concept without the federal Program. Titled the "340B Nondiscrimination Act," Oklahoma's law specifically prohibits drug manufacturers from engaging in conduct with respect to the "federal 340B drug discount program," "340B entit[ies]," and "340B drug[s]"—words the State defines by reference to the federal 340B statute. H.B. 2048 §§ 1, 2(1)–(2), 4. And by forcing 340B drug manufacturers to allow unlimited commercial contract pharmacies to acquire their discounted 340B drugs (a requirement Congress chose to omit from the 340B Program), H.B. 2048 overrides the 340B offer structure Congress established. It eliminates manufacturers' federally permitted discretion and dictates new terms under which entities receive discounted 340B drugs.

Congress's decision not to impose contract-pharmacy obligations was not an open door for states like Oklahoma to impose their own. After all, the 340B Program prescribes a condition for manufacturers' participation in other federal healthcare programs—so what it does *not* require is just as important as what it *does* require. *See Novartis*, 102 F.4th at 460 ("We think that [Congress's] silence preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions."). Put differently, the 340B Program is an ostensibly voluntary scheme where manufacturers agree to a specific set of obligations in exchange for the opportunity to participate in Medicaid and Medicare. By adding an extra obligation, H.B. 2048 changes the terms of Congress's deal. In no way did Congress invite states to append such requirements to its Program.

Oklahoma cannot escape this preemption problem by characterizing H.B. 2048 as a mere "delivery" regulation. For starters, *any* state regulation of the terms of 340B offers (even regulations framed as 340B-specific "delivery" requirements) intrudes on the purely federal 340B field.[12] But regardless, Oklahoma's statute actually regulates drug *prices*, not drug delivery. As the Southern District of West Virginia explained while enjoining a similar law, manufacturers "already deliver" their "drug products to contract pharmacies" throughout the state. *Morrisey*, 760 F. Supp. 3d at 455–56; *see* Ex. 1 ¶ 7. Oklahoma's perceived issue, then, is not insufficient distribution to pharmacies; it is that manufacturers demand normal commercial *prices* for such deliveries. H.B. 2048 thus defines the drugs at issue by their "reduced prices." H.B. 2048 § 2(1). So AbbVie risks violating H.B. 2048 "not by withholding drugs from contract pharmacies, but by refusing the 340B discount when delivering its drugs to those pharmacies." *Morrisey*, 760 F. Supp. 3d at 456. The law necessarily "regulates price, not delivery." *Id.* at 455.

Underscoring the fact that H.B. 2048 regulates drug pricing is the "replenishment model" used in most 340B contract-pharmacy arrangements. Under that model, pharmacies dispense all drugs from the same general inventory; they do not maintain separate stocks of 340B-priced drugs. Ex. 1 ¶¶ 8, 15f; Ex. 13 (Pedley Decl.) ¶¶ 3–11. Only on the back end do pharmacies guesstimate (using a secret algorithm) how many drugs they think were dispensed to 340B-eligible patients. Ex. 1 ¶¶ 9, 15b. The pharmacy or

[12] To be sure, a generally applicable delivery regulation—such as a state law requiring temperature-controlled trucks and inspections for drug-delivery vehicles—would not be preempted. H.B. 2048 simply is not such a law.

covered entity then demands "replenishment" of its inventory at the 340B price—and H.B. 2048 forces manufacturers to honor that demand. *Id.* ¶¶ 10–12. Because the drug has already been delivered to the pharmacy (and dispensed to a patient), the only thing H.B. 2048 could possibly impact is that drug's *price*.

At bottom, Oklahoma is bootstrapping a federal Program. In the State's view, Section 340B did not go far enough to maximize revenue for Oklahoma entities and pharmacies. But instead of exercising its police powers to create its own drug-discount scheme with new incentives, Oklahoma simply added (without permission) new contract-pharmacy requirements to expand Congress's 340B Program. That cannot stand.

Conflict Preemption. H.B. 2048 is also conflict preempted because it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona*, 567 U.S. at 399. Oklahoma's law conflicts with the 340B Program in several ways.

1. First, Oklahoma frustrates Congress's judgment by expanding the 340B Program's burden on manufacturers. In crafting 340B, Congress struck a careful balance between multiple competing interests: Congress wanted to ensure that certain healthcare providers could obtain below-market prices on drugs. But at the same time, it *needed* to incentivize drug manufacturers to participate in the ostensibly voluntary Program. So Congress defined the Program's scope and obligations—including any contract-pharmacy obligations (or lack thereof)—broadly enough to meet its goals of benefitting particular providers but narrowly enough to prevent overburdened manufacturers from withdrawing from the Program altogether. That limited scope is "no less a part" of Congress's "purpose"

than its substantive end goal of drug discounts. *Rapanos v. United States*, 547 U.S. 715, 752 (2006). The 340B Program thus has "twin federal purposes" of providing discounts to covered entities and protecting manufacturers. *Morrisey*, 760 F. Supp. 3d at 452. Oklahoma obstructs Congress's aims by skewing that balance and emphasizing only one of 340B's ends to the exclusion of the other.

2. Next, H.B. 2048 interferes with Congress's desire for a unified 340B enforcement scheme. As the Supreme Court explained in *Astra*, Congress vested HHS with exclusive authority to "oversee compliance with the 340B Program." 563 U.S. at 117. That is because Congress wanted to ensure "centralized enforcement in the government" and hoped to administer 340B "harmoniously and on a uniform, nationwide basis." *Id.* at 119–20. Congress also specifically delineated which tools HHS could use: audits, dispute resolution, and civil penalties. *See* 42 U.S.C. § 256b(d)(l)(B)(v)–(vi), (d)(3).

Oklahoma tramples on Congress's choices by installing its own parallel enforcement scheme to police 340B transactions. H.B. 2048 empowers the Oklahoma Attorney General to create regulations, investigate manufacturers for their 340B conduct, and impose state-law sanctions in state tribunals. *See* H.B. 2048 § 5(B). Oklahoma officials can also pursue *criminal* penalties against manufacturers for 340B activities—something Congress did not empower even HHS to do. Okla. Stat. tit. 36, § 117; *see Arizona*, 567 U.S. at 404–05 (finding conflict where a state imposed misdemeanor penalties for conduct that the federal government regulated with only civil consequences); *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 380 (2000) ("'Conflict is imminent' when 'two separate remedies are brought to bear on the same activity.'" (citation omitted)).

Making matters worse, Oklahoma officials must interpret and apply federal 340B law in executing H.B. 2048. For example, AbbVie might defend itself in an H.B. 2048 proceeding by arguing that the entity who ordered drugs was engaging in unlawful diversion or was otherwise ineligible for 340B discounts. *See* H.B. 2048 §§ 2(2), 4 (no violation absent involvement of entity "authorized to participate in the federal 340B drug discount program"); *see also Morrisey*, 760 F. Supp. 3d at 454 (recognizing that statutes structured like H.B. 2048 call upon state officials to decide federal 340B issues). As *Morrisey* aptly concluded, such overlapping enforcement regimes obstruct Congress's aims. The result is a hodgepodge of state and federal adjudicators deciding the same purely federal questions in potentially inconsistent ways. And that "risk of conflicting results cuts against Congress's vision of 'centralized enforcement' that *Astra* found as necessary to execute the 340B Program." *Morrisey*, 760 F. Supp. 3d at 458.

3. Oklahoma's law also creates a conflict by restricting manufacturers' access to the federal 340B dispute-resolution scheme. H.B. 2048 broadly prohibits any "interfere[nce]" with contract pharmacies (and other pharmacies contracted with contract pharmacies). *See* H.B. 2048 § 4(B). Although that provision is too vague to meaningfully understand, *see infra* at I.C, it arguably prohibits manufacturers from demanding claims data as a condition of transferring discounted drugs to contract pharmacies. That is a problem because the 340B Program contemplates manufacturers demanding claims data: Before accessing the federal dispute-resolution system (the exclusive means for enforcing 340B violations), manufacturers must first "conduct an audit." 42 U.S.C. § 256b(d)(3)(B)(iv). And before conducting an audit, the manufacturer must have

"reasonable cause" to suspect a violation—which requires access to claims data. *See* 61 Fed. Reg. 65406, 65409–10 (Dec. 12, 1996). So, to the extent that H.B. 2048 obstructs manufacturers from requiring claims data, it effectively forecloses manufacturers' only avenue to pursue claims against covered entities for violations of the 340B Program's requirements. That is one reason why *Morrisey* found that West Virginia's 340B claims-data restriction conflicts with federal law. *See* 760 F. Supp. 3d at 451–53.

4. Oklahoma cannot excuse these conflicts by leaning on the Eight Circuit's conclusion that federal law does not preempt Arkansas's contract-pharmacy statute. *See PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024). Even if *McClain* were binding or persuasive (it is neither), the case is distinguishable. Among other things, the Eighth Circuit's conclusion rested on its assumptions that covered entities maintain title to drugs held at contract pharmacies and enjoy principal-agent relationships with those pharmacies. *Id.* at 1142–44. Even if that were true in Arkansas, it is certainly not true here: The record in *this* case shows that covered entities in Oklahoma do not maintain title to drugs held at contract pharmacies, and contract pharmacies do not operate as covered entities' agents.[13] H.B. 2048 imposes no such requirements, either. *McClain*'s analysis is thus inapposite. *See Morrisey*, 760 F. Supp. 3d at 458–59 (criticizing *McClain*'s conclusory analysis and deeming it "distinguishable"). Federal law preempts H.B. 2048.

[13] Ex. 1 ¶¶ 12–13, 16; Ex. 14 (2024 340B Report Article) at 5–6 (counsel for covered entities admitting that "the title to 340B drugs transfers to the contract pharmacy at the time it is taken into inventory"); *BancOklahoma Mortg. Corp. v. Cap. Title Co.*, 194 F.3d 1089, 1104 (10th Cir. 1999) (agency requires control by principal and action on his behalf); *Northstar Mgmt., Inc. v. Vorel*, 2022 WL 18110173, at *6 (W.D. Okla. Nov. 7, 2022) (agents generally cannot commingle property with their principal's).

B. Oklahoma's Law Effects an Unconstitutional Taking.

H.B. 2048 also effects an unconstitutional taking because it compels AbbVie and other manufacturers to make sales at 340B-discounted prices under terms they would never otherwise accept, resulting in windfall private gains for commercial pharmacies and other private entities. *See* Ex. 15 (N.C. Treasury Report) at 8, 10, 15; Ex. 16 (2024 NEJM Article) at 338; Ex. 17 (Senate Letter to CVS).

The drugs that AbbVie manufactures are its property—protected by the Takings Clause like any other private property. *See Horne v. Dep't of Agric.*, 576 U.S. 350, 358 (2015). And the most basic principle of takings law is that a government may not take property from private party A and give it to private party B. *See Kelo v. City of New London*, 545 U.S. 469, 477 (2005) ("[T]he sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation."); *Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798) (same). Such takings are always unconstitutional: "No amount of compensation" can cure them. *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005).

Here, Oklahoma's law effects a physical taking of AbbVie's property by forcing AbbVie to transfer its pharmaceutical products to private third parties for discounted prices under conditions AbbVie would never voluntarily accept. H.B. 2048 prohibits AbbVie from denying or restricting the "acquisition" of its drugs at 340B-discounted prices by a "340B entity"—a term defined to include both covered entities and commercial contract pharmacies. H.B. 2048 §§ 2(1)–(2), 4(A). H.B. 2048 thus compels sales or transfers of AbbVie's drugs at the 340B-discounted price that would not otherwise occur: Absent

Oklahoma's law, if a covered entity demanded unlimited contract-pharmacy access, AbbVie would refuse and no sale at the 340B-discounted price would take place. But H.B. 2048 will force AbbVie to accept the demand and relinquish its drugs to a commercial pharmacy at the discounted price.

That offends the Takings Clause. For starters, Oklahoma neglects to provide AbbVie any compensation for its physical taking, much less the "just compensation" required by the Constitution. *See Knick v. Township of Scott*, 588 U.S. 180, 189–90 (2019) (constitutional violation occurs the instant that a government takes private property "without paying for it"). More fundamentally, H.B. 2048 reflects the sort of private A-to-B takings that are inherently unconstitutional because they serve no recognized public use. While the Supreme Court has occasionally permitted (compensated) transfers of property to private parties for carefully circumscribed reasons—such as curing blight or breaking up land oligopolies—it flatly forbids takings that simply "confer[] a private benefit on a particular private party" or "benefit a particular class of identifiable individuals." *Kelo*, 545 U.S. at 477–78 (citation omitted). H.B. 2048 does just that by enriching certain private covered entities and pharmacies at manufacturers' expense. This is not a "public use" recognized in American law. *See Baker v. City of McKinney*, 84 F.4th 378, 383 (5th Cir. 2023) (collecting recent Supreme Court cases).

Underscoring the public-use problem, neither covered entities nor pharmacies pass those windfall discounts onto needy patients or have any duty to use 340B revenue for

charity or uncompensated care.[14] Instead, covered entities generally direct their 340B profits into general operating budgets, Ex. 23 (2025 Senate Report) at 10, while commercial pharmacies annually reap hundreds of millions of 340B dollars as private commercial revenue, *id.* app. 106. Tellingly, the 340B Program's post-2010 expansion has not even focused on needy communities: The recent growth in contract pharmacies (and off-site covered-entity hospital facilities) is instead concentrated in Oklahoma's most affluent areas. Ex. 24 (Chen Expert Report) at 4–5. And the explosion of 340B profits is not correlated with any meaningful increase in covered entities' charity-care spending or improvements in patient outcomes. Ex. 25 (Chandra Expert Report) at 5–6.

Oklahoma cannot evade that Takings Clause violation by pretending AbbVie somehow consented to H.B. 2048's obligations by voluntarily participating in the federal 340B Program. Although voluntarily accepting a government benefit in exchange for giving up property rights can extinguish a takings claim against the government who conferred the bargained-for benefit, *see Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984), it cannot justify separate state-imposed requirements without an accompanying state-law benefit. Thus, the "voluntary participation" doctrine does not help Oklahoma. Even if AbbVie voluntarily accepted federal 340B obligations as a condition of participating in federal Medicare and Medicaid programs, H.B. 2048 imposes additional *state* burdens with "no additional benefit." *See Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023); *see also Va. Hosp. & Healthcare Ass'n v. Roberts*, 671

[14] *E.g.*, Ex. 18 (Conti-Bach Article); Ex. 19 (2018 NEJM Article); Ex. 20 (2022 AIR Report); Ex. 21 (2021 AJMC Article); Ex. 22 (2017 COA Report).

F. Supp. 3d 633, 666 (E.D. Va. 2023) ("[T]hose *state law* … requirements have no bearing on whether providers' participation in Medicaid and Medicare are voluntary as a matter of *federal* law."). In no way did AbbVie sign up for Oklahoma's scheme.[15] H.B. 2048 effects an improper taking and should be enjoined.

C. Oklahoma's Law Is Void For Vagueness.

H.B. 2048 also offends AbbVie's due process rights because it is impermissibly vague. The Fourteenth Amendment's Due Process Clause forbids states from "depriv[ing] any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. A state statute violates that clause if it is so vague that the law "fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits" or "authorizes or even encourages arbitrary and discriminatory enforcement." *Wyo. Gun Owners v. Gray*, 83 F.4th 1224, 1233 (10th Cir. 2023). H.B. 2048 fails on both counts. It is thus unconstitutionally vague—on its face and as applied to AbbVie's ability to enforce its contract-pharmacy and claims-data policies.

In a key provision, H.B. 2048 vaguely prohibits manufacturers from "interfering" with pharmacies: "A manufacturer shall not interfere with a pharmacy contracted with a 340B entity." H.B. 2048 § 4(B). For several reasons, that "interference" prohibition falls short of providing the requisite clarity to pass constitutional muster.

---

[15] *See AbbVie Inc. v. Fitch*, No. 24-60375 (5th Cir. oral arg. Apr. 2, 2025) at 22:55–23:23 (Chief Judge Elrod explaining AbbVie agreed to sell its drugs "in the program that they signed up through Congress with," but asking "they didn't ever agree with Mississippi to sell them the product at this rate … where did they do that?"), https://tinyurl.com/57fee5wd.

To start, Oklahoma's statute provides no guidance on what "interfere" means. "Interfere" is not defined in H.B. 2048 or in the relevant title of the Oklahoma code. Nor are related terms like "interference" or "interfering." And the term "interfere"—as used in § 4(B)—is not even part of a list that could provide context clues as to its meaning. Unsurprisingly, courts regularly acknowledge that statutes run afoul of the vagueness doctrine when they amorphously prohibit undefined "interference." *See, e.g.*, *Carolina Youth Action Project v. Wilson*, 60 F.4th 770, 786 (4th Cir. 2023) (holding unconstitutionally vague a law that prohibited "interfer[ing] with or [disturbing] in any way or in any place the students or teachers of any school or college in this State"); *Corp. of Haverford Coll. v. Reeher*, 329 F. Supp. 1196, 1208–09 (E.D. Pa. 1971) (collecting cases). This case is no different. Without any objective criteria or illustrative examples, AbbVie is left to divine the meaning through trial and error. Meanwhile, the Oklahoma Attorney General has free rein to selectively and arbitrarily prosecute a wide variety of conduct that could potentially be considered "interference."

Making matters worse, H.B. 2048 contains no apparent scienter requirement. *See, e.g.*, *Galbreath v. Oklahoma City*, 568 F. App'x 534, 541 (10th Cir. 2014) (concluding that absence of scienter requirement made it more likely that law was unconstitutionally vague). It does not, for example, require interference to be purposeful or intentional. So AbbVie could be prosecuted for accidentally "interfering" (whatever that means) with a contract pharmacy. And that is hardly a theoretical risk. Covered entities and contract pharmacies are fiercely resistant to making their contracts available to manufacturers or the public.

That aggravates the already glaring vagueness problem because manufacturers have no idea what terms they might potentially "interfere" with.

On top of that, H.B. 2048's interference provision is not textually limited to contract pharmacies or even 340B-related contracts—indeed, it utterly fails to articulate *what* manufacturers are prohibited from "interfering" with. By its terms, the law prohibits interference "with a pharmacy contracted with a 340B entity." H.B. 2048 § 4(B). Yet "340B entity" is already defined to include "any pharmacy contracted with [a] participating entity to dispense drugs purchased through the 340B drug discount program." *Id.* § 2(2). Thus, AbbVie risks serious sanctions by somehow "interfering" with *any* pharmacy (even a pharmacy that does not dispense 340B drugs) if that pharmacy happens to have some sort of unrelated private contractual arrangement with a different commercial pharmacy that dispenses 340B drugs. That is an indecipherable mess. It is impossible for AbbVie to operate its pharmaceutical business and interact with pharmacies without potentially stumbling over a legal tripwire. So even if manufacturers could somehow divine what "interfere" means (they can't), and even if manufacturers possessed perfect knowledge about the terms of 340B contracts between covered entities and contract pharmacies (they don't), § 4(B) would *still* be unconstitutionally vague.

Finally, H.B. 2048's vagueness is especially egregious because it authorizes Oklahoma officials to impose *criminal* penalties for violations. *See* Okla. Stat. tit. 36, § 117. Courts demand special clarity of criminal laws: "Criminal statutes must be more precise than civil statutes because the consequences of vagueness are more severe." *United States v. Lesh*, 107 F.4th 1239, 1247 (10th Cir. 2024) (internal citations and quotation

marks omitted). After all, "criminal responsibility should not attach where one could not reasonably understand that his contemplated conduct is proscribed." *Id.* Absent clarity about the statute's meaning, the Oklahoma Attorney General will be free to cherry pick policies for criminal enforcement actions under H.B. 2048.

At bottom, H.B. 2048's impenetrable text makes it impossible to know what it prohibits and how it might be enforced. It opens the door to selective prosecutions. And it holds the specter of civil and *criminal* liability over AbbVie's head for virtually any interaction AbbVie has with virtually any pharmacy. Such an arrangement hardly comports with due process.

II. H.B. 2048 WILL CAUSE ABBVIE IRREPARABLE HARM.

AbbVie will suffer irreparable harm absent a preliminary injunction. Harm is irreparable "'when the injury cannot be adequately atoned for in money' or when 'the district court cannot remedy the injury following a final determination on the merits.'" *Prairie Band of Potawatomi Indians v. Pierce*, 253 F.3d 1234, 1250 (10th Cir. 2001) (brackets and internal citation omitted). AbbVie faces irreparable harm in two ways.

First, H.B. 2048 will cause irreparable harm by depriving AbbVie of its constitutional rights. "Any deprivation of any constitutional right" is itself an irreparable injury—"no further showing" is required. *Free The Nipple-Fort Collins v. City of Fort Collins*, 916 F.3d 792, 805–06 (10th Cir. 2019) (citing *Awad v. Ziriax*, 670 F.3d 1111, 1131 (10th Cir. 2012)); *see also Occidental Petroleum Corp. v. Cities Serv. Co.*, 1982 WL 1376, at *8 (W.D. Okla. Dec. 20, 1982) (irreparable harm existed both because state law was unconstitutional and because it deprived the plaintiff of rights under a federal statute). As

explained above, H.B. 2048 effects an ongoing unconstitutional taking of AbbVie's property, is so vague that it offends AbbVie's due process rights, and unlawfully imposes burdensome obligations and punishments that clash with the federal 340B statute. Any one of those constitutional violations amounts to irreparable harm. *See Free The Nipple*, 916 F.3d at 805–06. Relatedly, H.B. 2048 presents a Hobson's choice: comply with an unconstitutional mandate or risk enforcement. That dilemma is itself irreparable harm. *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992) (finding irreparable harm where businesses forced to choose between complying with preempted state statute or continually exposing themselves to state-law liability for violating the law).

Second, irreparable harm exists because AbbVie will incur unrecoverable compliance costs absent an injunction. *Chamber of Commerce of U.S. v. Edmondson*, 594 F.3d 742, 770–71 (10th Cir. 2010). H.B. 2048's enforcement would impose staggering costs on AbbVie. In the past year alone, compliance with similar laws in states like Mississippi and Missouri cost $31.1 million and $35 million, respectively. AbbVie estimates that compliance with Oklahoma's H.B. 2048 will cost approximately $45.7 million in the next year. Ex. 1 ¶¶ 23–26. And across over a dozen different states' 340B laws—each with its own differing requirements and penalties—AbbVie stands to lose well into the hundreds of millions of dollars. Refusal to comply would likely expose AbbVie to catastrophic civil and criminal penalties.

This harm cannot later be undone. There exists no mechanism for forcing covered entities or commercial pharmacies to refund AbbVie for unlawfully received discounts or other compliance costs if H.B. 2048 is ultimately invalidated. And the doctrine of

sovereign immunity bars AbbVie from recovering its losses from Oklahoma. *See Edmondson*, 594 F.3d at 770–71 ("Imposition of monetary damages that cannot later be recovered for reasons such as sovereign immunity constitutes irreparable injury." (citing *Kan. Health Care Ass'n v. Kan. Dep't of Social & Rehab. Servs.*, 31 F.3d 1536, 1543 (10th Cir. 1994))). These irreversible costs carry lasting consequences: The lost revenue will undercut AbbVie's business model and hurt its ability to invest in the research and development of future life-saving products. Ex. 1 ¶ 21.

III. THE EQUITIES AND THE PUBLIC INTEREST FAVOR ABBVIE.

The remaining preliminary injunction factors weigh in AbbVie's favor, too. "Oklahoma does not have an interest in enforcing a law that is likely constitutionally infirm," so a preliminary injunction will not harm it. *Edmondson*, 594 F.3d at 771. Plus, "the public interest [is] served by enjoining the enforcement of the invalid provisions of state law," *id.*, and it is "always in the public interest to prevent the violation of a party's constitutional rights," *Free the Nipple*, 916 F.3d at 807. Oklahoma likewise cannot rely on imagined harm to its citizens. There is no evidence that needy patients—in Oklahoma or elsewhere—benefit from the unlimited use of contract pharmacies. *E.g.*, Exs. 2–10, 18–22, 24–25. Nor does H.B. 2048 require covered entities and their contract pharmacies to use 340B revenue on charity or uncompensated care, or for other altruistic purposes. The State has no legitimate interest in enriching private parties at the expense of manufacturers and patients. The public interest and equities thus favor a preliminary injunction.

CONCLUSION

The Court should grant AbbVie's motion for a preliminary injunction.

Dated: July 24, 2025

Respectfully submitted,

/s/ Paul DeMuro

Paul DeMuro
FREDERIC DORWART, LAWYERS PLLC
124 E. 4th Street
Tulsa, OK 74103
Telephone: (918) 583-9957
Email: pdemuro@fdlaw.com

Matthew S. Owen, P.C. (*pro hac vice* forthcoming)
Meredith M. Pohl (*pro hac vice* forthcoming)
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Telephone: (202) 389-5000
Email: matt.owen@kirkland.com
meredith.pohl@kirkland.com

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was electronically filed with the Clerk of the Court via the Court's CM/ECF system, which sent notification of such filing to all counsel of record by electronic means.

/s/ Paul DeMuro
Counsel of Record